

SPL Process ER/DL Meeting Meeting Minutes July 29, 2015

Chair of today's meeting: Pat Cowall

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Teleconference information: How to mute/unmute

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Link to the SPL wiki:

<http://spl-work-group.wikispaces.com/share/view/51351516>

Agenda:

1. Lonnie Smith – Product Indexing files.

Lonnie presented on the product indexing files at both the July 15 meeting and at the August 26th meeting. The notes and the screen shots are included in August 26th meeting minutes.

2. Jeff Ho (Navitas) – IDMP update

See the slide deck (separate file) Jeff used in his presentation

Additional points made in the discussion:

- IDMP is a common language that describes the product and key information about the product. It will be used across all types of reporting.
- Implementation in EU is July, 2016, but this is expected to be moved out to 2018.
- Implementation Guide is expected out in early 2016.

Questions and answers:

- Have you done a comparison of IDMP versus SPL? How similar/different are they?

Comments from Jeff Ho:

- High overlap between IDMP and SPL
- SPL seems to be the place to report this common vocabulary. Because the data is already in SPL, we know how to gather the information, at least for the US.

Comments from Joel Finkle:

- Existing SPL is ISO compliant.
- FDA will not be in a hurry to implement because it will need to go through the regulatory approval process

- Expect > 2 years after guidance to required implementation

Comments from Vada Perkins:

- We mapped IDMP to Common Product Model (CPM)
 - We mapped CPM to SPL in 2012.
 - It was intentional to try make them consistent
 - In R7, we only added the EU IDMP requirements
- Will the data dictionaries used for SPL be the same as for IDMP?
 - This is being sorted out in the first wave of development. Stay tuned!